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| APPLICATION NO.           | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.        |  |
|---------------------------|-----------------|----------------------|-------------------------|-------------------------|--|
| 10/021,607                | 12/12/2001      | Darcy Wayne Greep    | 14458.41                | 7181                    |  |
| 22913                     | 7590 12/17/2002 |                      |                         | •                       |  |
| WORKMAN NYDEGGER & SEELEY |                 |                      | EXAMINER                |                         |  |
| 60 EAST SOU               |                 |                      | ROANE, AARON F          |                         |  |
| SALTLAKE                  | CITY, UT 84111  |                      | ART UNIT                | PAPER NUMBER            |  |
|                           |                 |                      | 3739                    |                         |  |
|                           |                 |                      | DATE MAILED: 12/17/2002 | DATE MAILED: 12/17/2002 |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                  |           |  | SM.       |  |  |  |
|--|------------------|-----------|--|-----------|--|--|--|
|  | Application I    | No.       | Applicant(s)   |           |  |  |  |
| .1   | 10/021,607       |           | GREEP ET AL.   |           |  |  |  |
| Office Action Summary  | Examiner         | <u> </u>  | Art Unit   |           |  |  |  |
|  | Aaron Roane      |           | 3739   |           |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |                  |           |  |           |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  |                  |           |  |           |  |  |  |
| 1) Responsive to communication(s) filed on <u>12 L</u>   | December 200     | )1 .      |  |           |  |  |  |
| ·— ·   | nis action is no |           |  |           |  |  |  |
| 3) Since this application is in condition for allowa   | ance except fo   | or formal | matters, prosecution as to the r   | merits is |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>   |                  |           |  |           |  |  |  |
| 4)⊠ Claim(s) <u>1-38</u> is/are pending in the application.  |                  |           |  |           |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |                  |           |  |           |  |  |  |
| 5) Claim(s) is/are allowed.  |                  |           |  |           |  |  |  |
| 6) Claim(s) <u>1-5,7-23,25-31 and 36-38</u> is/are reject  | cted.            |           |  |           |  |  |  |
| 7)⊠ Claim(s) <u>6,24 and 32-35</u> is/are objected to.   |                  |           |  |           |  |  |  |
| 8) Claim(s) are subject to restriction and/o   | or election requ | uirement  | t.   |           |  |  |  |
| Application Papers   |                  |           | ·  |           |  |  |  |
| 9) The specification is objected to by the Examine   |                  | iostod to | by the Everniner   |           |  |  |  |
| 10) The drawing(s) filed on is/are: a) accelling a |                  |           |  |           |  |  |  |
| 11) The proposed drawing correction filed on   |                  |           |  |           |  |  |  |
| If approved, corrected drawings are required in re   |                  |           |  |           |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.  |                  |           |  |           |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |                  |           |  |           |  |  |  |
| 13) Acknowledgment is made of a claim for foreign  | n priority unde  | er 35 U.S | S.C. § 119(a)-(d) or (f).  |           |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   | ' '              |           |  |           |  |  |  |
| 1. Certified copies of the priority documents have been received.  |                  |           |  |           |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |                  |           |  |           |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |                  |           |  |           |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).   |                  |           |  |           |  |  |  |
| a) The translation of the foreign language provisional application has been received.  |                  |           |  |           |  |  |  |
| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |                  |           |  |           |  |  |  |
| Attachment(s)  |                  |           |  |           |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>   | 5)               |           | rview Summary (PTO-413) Paper No(s).<br>ce of Informal Patent Application (PTO-<br>er: |           |  |  |  |

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### **DETAILED ACTION**

# Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of U.S. Patent No. 10/021532. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the product and method of coating an electrosurgical tip that deal with either a hydrophilic/hydrophobic mix polymer or a water-soluble polymer. Other than this difference, which is not a major distinction, the dependent claims read almost identically

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12, 29-33 and 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: prior positive recitation of and further limitation to that particular water-soluble polymer type.

Regarding claims 8-12, the base claim 7, the base claim for claims 8-12, recites the group of water-soluble polymer types. However, before a particular limitation to water-soluble polymer can be made, a prior limitation to the particular water-soluble polymer type to which the recited limiting water-soluble polymer belongs, must be made.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 1-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garito et al. (USPN 4,754,754) in view of Jones et al. (USPN 6,132,427) in further view of Fan et al. (USPN 5,295,978).

Regarding claim 1,2, 4, 7 and 11, 17, 22, 29, 30, Garito et al. disclose the claimed invention including an "RF output socket" (11) and a hand piece (20), see col. 2, lines 49-68. Garito et al. fail to disclose a multi character coated electrode tip. Jones et al. teach the method, step or use of a device including a multi-layered coated tip electrode with a base coating (16) of ceramic in order to provide a wear resistant cover, see col. 3, lines 4-31. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings.

Regarding claim 3, Garito et al. in view of Jones et al. disclose the claimed invention, see col. 4, lines 13-23.

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Regarding claims 5 and 15, 18, 31, 38, Garito et al. disclose the claimed invention except for the pores base material wherein the multi-character material occupies at least a portion of the pores. Jones et al. teaches the inclusion of a conductive tip comprising a porous metal of roughened stainless steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. The hydrophilic/hydrophobic material of Fan et al. will inherently occupy the pores. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al., as taught by Jones et al. to provide the inclusion of a conductive tip comprising a porous metal of roughened stainless steel to the electrode tip with a multi-layered coating in order to improve wear resistance, and as further taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers that inherently occupy the pores in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings.

Regarding claims 8 and 21, 37, Garito et al. in view of Jones et al. disclose the claimed invention except for the water-soluble polymer comprising at least one of polyethylene oxide, polyethylene glycol or a copolymer of ethylene oxide. Fan et al. teach a method and use of "poly(ethylene oxide)" as the water-soluble polymer in order to overcome the shortcomings of earlier coating polymers, see col. 3, lines 28-43. Therefore at the time of

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the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Garito el al. in view of Jones et al., as taught by Fan et al. to use "poly(ethylene oxide)" as the water-soluble polymer in order to overcome the shortcomings of earlier coating polymers.

Regarding claims 12, 13, 27 and 28 Garito et al. in view of Jones et al. disclose the claimed invention except for the inclusion of carrying deposits of a factor that further includes at least one of an antibiotic, a healing, an anti-adhesion, an anti-tumor or a tumor necrosis factor. Fan et al. teaches the use biocompatible polymeric abrasion resistant surfaces including formulated additives with antimicrobial or other pharmaceutically effective agents" in order to overcome the shortcomings of earlier coatings and provide a more varied method and wider range of coatings and their properties, see col. 2, lines 43-68. Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al in view of Jones et al., as taught by Fan et al. to use biocompatible polymeric abrasion resistant surfaces with included formulated additives with antimicrobial or other pharmaceutically effective agents" in order to overcome the shortcomings of earlier coatings and provide a more varied method and wider range of coatings and their properties.

Regarding claims 14 and 25, Garito et al. in view of Jones et al. disclose the claimed invention except for explicitly stating that water-soluble polymer provides a low shear, sacrificial layer to the tip. Fan et al. teach the method, step or coating of with a water-

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soluble polymer material which "becomes lubricious when exposed to body fluid". The recitation of lubricious nature of the polymer coating meets the claimed limitation.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al. in view of Jones et al., as taught by Fan et al. to use a polymeric coating that becomes lubricious when exposed to body fluid in order to provide improved coating performance.

Regarding claims 16 and 260, Garito et al. in view of Jones et al. disclose the claimed invention except for using a multi-character material that includes a charged unit. Fan et al. teach the method, step or device that includes a metallic or ammonium ion, co. 5, lines 41-68 and col. 6, lines 1-3.

Regarding claims 19 and 20, Garito et al. in view Jones et al. disclose the claimed invention that includes a conductive tip comprising a porous metal of roughened stainless steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25. Furthermore, Jones et al. disclose a method of applying the ceramic coating layer over top the roughened substrate by spraying using a plasma gun. Therefore, the ceramic coating layer is inherently porous since it lies atop the roughened substrate.

Regarding claim 36, Garito et al. in view of Jones et al. disclose the claimed invention except for the multi-character material coating and the coating application process comprising a, dip, spray, brushing, wiping or adsorption process. Fan et al. teach the use

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of a hydrophilic/hydrophobic polymeric combination material and a coating application process by dipping, claims 1 and 5 and col. 11, lines 44-54. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Garito et al. in view of Jones et al., as taught by Fan et al. to improve the coating by using a combination of hydrophilic and hydrophobic polymers and to coat by using a dipping process in order to provide an abrasion resistant coating to overcome the shortcomings of earlier coatings.

Regarding claims 7-12, 28-33 and 44-49, Jones et al. discloses the claimed invention except for stating the explicitly recited water-soluble polymer or water-soluble polymer type. Fan et al. teach the method, step and use of a device with a wide variety of water-soluble polymers specifically identified for the coating, see col. 3-22. The possible water-soluble polymer types listed in claims 7, 28 and 44 and some of the type constituents listed are shown on pages 19 and 20 of applicant's disclosure. The choice or limitation to one of the types of water-soluble polymer and the further limitation to a specific water-soluble polymer within a given type is not considered critical since the list is very large and not particularly substantiated by applicant. Therefore at the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use any one of the water-soluble polymers recited in Fan et al. because applicant has not disclosed that the recited water-soluble polymers provide an advantage or solves a particular problem (over the Fan et al. reference).

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# Allowable Subject Matter

Claims 6, 16, 24, 26 and 32-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references may prove useful. Allen (USPN 4,314,559), Lontine et al. (USPN 5,713,895) and (USPN 6,139,547) disclose coated substrates containing pores. Both Sansom et al. (USPN 5,197,962) and Morris (USPN 6,106,523) disclose composite coated devices and the methods of coating such, while Sutcu et al (USPN 5,549,604) disclose an amorphous silica coating. Finally Fan et al. (USP 5,509,899 5,558,900 and 5,731,087) deal give a fair review of the coating compounds, methods of and improvements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9272 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A.R. **A. Z**. December 12, 2002

MICHAEL PEFFLEN
PRIMARY EXAMINER